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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,723

08/11/2006

Dirk Muehlhoff

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EXAMINER

HUNTER, RONALD A

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,723	Applicant(s) MUEHLHOFF ET AL.	
	Examiner RONALD HUNTER	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/24/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/24/2006 & 9/23/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to because the reference characters "g", "ga" and "gp" are not found in the specification. For purposes of examination, examiner has interpreted these characters as "9", "9a", and "9p". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 12, 15, 16, & 24 are objected to because of the following informalities:

Claims 12, 15, 16, & 24 – recite a “transparent material” and a “material.” It is unclear if these references are analogous. Consistency with terminology is suggested.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18-29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In claims 18 & 24, line 2 - applicant positively recites part of a human, i.e. “a transparent material (cornea)”. Thus claims 18-29 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "the desired location" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "the desired location" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 22 recites the limitation "the spiral " in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by **Juhasz et al. (US 5,993,438 A)**.

Regarding claims 12, 15, Juhasz et al. disclose a method for performing photodisruption (*forming a cut*) and removal of tissue in a stroma (*transparent material o*) of a cornea of an eye using a pulsed laser beam, which is sequentially focused to individual spots at a plurality of points in the stroma (*column 1, lines 63-67*). Examiner has interpreted a pattern of spots in each layer positioned in a spiral pattern as, *adjusting the focal point three-dimensionally along a main axis and elevation lines parallel to the optical axis*, and which is substantially centro-symmetric (*substantially at a right angle*) to the optical axis of the eye. The result is a plurality of substantially flat layers of photodisrupted stromal tissue, each layer being substantially perpendicular and substantially symmetric to the optical axis (*Fig. 2; column 3, lines 29-34*).

Regarding claims 13, 16, Juhasz et al. disclose a method for performing photodisruption (*forming a cut*) and removal of tissue in a stroma of the cornea in the eye (*column 1, lines 63-67*), wherein the examiner has interpreted the stroma is *posteriorly located in respect to the epithelium of the cornea along the optical axis*.

Regarding claims 14, 17, Juhasz et al. disclose the pattern of spots in each layer can be positioned in a spiral pattern which is substantially centro-symmetric to the optical axis of the eye. The result is a plurality of substantially flat layers of photodisrupted stromal tissue, each layer being substantially perpendicular and

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substantially symmetric to the optical axis. *Examiner has interpreted creating substantially flat layers in a spiral pattern as generating optical breakthroughs on anterior parts without obscuring the transparent material on posterior parts.*

Claims 18-29 are rejected under 35 U.S.C. 102(b) as being unpatentable by **Swinger et al. (6,325,792 B1)**.

Regarding claims 18, 20, & 24, Swinger et al. disclose an apparatus for corneal surgery (*column 1, lines 15-17*). A lasing medium of the pulsed laser apparatus uses lasing ions such as titanium, chromium or neodymium (for example, $\text{Ti}_3:\text{Al}_2\text{O}_3$, $\text{Cr}:\text{LiSrAlF}_6$, $\text{Nd}:\text{YLF}$, or similar lasers) (*column 36, lines 53-56*), the laser unit **100** includes a seed laser **102** and a scanner-amplifier laser **104** (*column 17, lines 16-17*), and the beam intensity controller **112** is coupled to a computer control unit **114**, which is suitably programmed to vary the intensity of the output surgical laser beam **S** as required for a particular surgical procedure (*Fig. 6; column 17, lines 50-53*) and spot **58** is then moved in a scanning motion under computer control along a spiral (*sinusoidal function*) (*Fig. 7, #619; column 25, lines 12 & 13*), wherein examiner has interpreted the spiral as extending along, a main axis that is at substantially right angles to, and elevation lines that are substantially parallel to, an optical axis.

Regarding claims 19 & 25, Swinger et al. disclose a zoom lens **106** may be placed in a number of suitable positions along the optical path of the laser beam between the laser unit **100** and a target (*Fig. 6; column 17, lines 24-26*) and deflectable

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mirrors (deflecting unit) may then be used to steer the surgical laser beam (*column 20, lines 16 & 17*).

The recitation "for adjusting the point substantially along the optical axis and for two-dimensional adjustment of the focal point substantially at right angles to the optical axis" is based on intended use. The structure disclosed by Swinger et al. would inherently perform as claimed when used in the same manner.

Regarding claims 21, 26 & 27, Swinger et al. disclose a spiral scanning motion under computer control coupled with a zoom lens and adjustable optics (*see figure 6, Fig. 7, #619; column 25, lines 12 & 13*), wherein examiner has interpreted the spiral as a deflection in one of two spatial directions according to a second substantially sinusoidal function, and in the other of the two spatial direction according to a substantially linear function having an oscillation or stepped function superimposed thereon.

Regarding claims 22, 23, 28 & 29, Swinger et al. disclose ablation proceeds from posterior to anterior within the cornea to avoid absorption of the beam energy by plasma. Thus, the beam spot is always moving into unablated tissue (*not obscured by previously created optical breakthroughs*) (*column 30, lines 60-63*).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related

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limitations of the applicant's claimed and disclosed invention: **Bille et al. (US 4,901,718**

A) teaches 3-dimensional laser beam guidance, **Juhasz et al. (US 2003/0014042 A1)**

teaches stromal laser photodisruption, **& Shimmick et al. (US 6,497,701 B2)** teaches a deflection unit.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUNTER whose telephone number is (571)270-7133. The examiner can normally be reached on Monday - Friday, 9:00am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD HUNTER/

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